

CLAIMS

- 1) A method for predicting a near future BG profile and the onset of hypoglycemia comprising the steps of:
  - monitoring and recording a BG history profile;
  - 5 monitoring and recording an insulin infusion and/or injection history profile;
  - monitoring and recording a HR history profile as an estimate of physical activity,
  - 10 monitoring and recording a HRV history profile as an estimate of sympathetic nervous system activity;
  - determining a predicated near future BG profile using a first predetermined bio-mathematical routine; and
  - evaluating the near future BG profile to predict the onset of hypoglycemia in the near future based on an assessed risk of hypoglycemia,
  - 15 wherein the assessed risk of hypoglycemia is determined using a second predetermined bio-mathematical routine.
- 2) The method of claim 1 further including the step of adjusting insulin infusion and/or injection rates based on the predicted near future BG profile and the predicted onset of hypoglycemia.
- 20 3) The method of claim 1 wherein the step of monitoring and recording HRV history profiles further includes the step of using an EKG to measure and evaluate the power spectra of RR time series as an estimate of HRV.
- 4) The method of claim 1 wherein the second predetermined bio-25 mathematical routine assesses the risk of hypoglycemia based on a Low BG Index which is determined using a BG Risk Function.
- 5) The method of claim 1 further comprising the step determining the assessed risk of hypoglycemia using the second predetermined bio-mathematical routine.

- 6) The method of claim 5 wherein the second predetermined bio-mathematical routine comprises the steps of:  
receiving and recording a BG history profile;  
transforming the BG history profile scale to obtain a symmetrical  
distribution scale;  
introducing a BG Risk Function to obtain a Low BG Index; and  
determining the assessed risk of hypoglycemia based on the Low BG  
Index.
- 7) A method for predicting a near future BG profile and the onset of  
hypoglycemia in the near future comprising the steps of:  
receiving data input regarding BG history, insulin infusion/injection  
history, HR history, and HRV history;  
evaluating the data input received using a first predetermined bio-  
mathematical routine to predict a near future BG profile; and  
evaluating the near future BG profile to predict the onset of  
hypoglycemia in the near future based on an assessed risk of hypoglycemia,  
wherein the assessed risk of hypoglycemia is determined using a second  
predetermined bio-mathematical routine.
- 8) The method of claim 7 wherein the second predetermined bio-  
mathematical routine assesses the risk of hypoglycemia based on a Low BG  
Index which is determined using a BG Risk Function.
- 9) The method of claim 7 further comprising the step of  
determining the assessed risk of hypoglycemia using the second predetermined  
bio-mathematical routine.
- 10) The method of claim 9 wherein the second predetermined bio-  
mathematical routine comprises the steps of:  
transforming the BG history profile scale to obtain a symmetrical  
distribution scale;  
introducing a BG Risk Function to obtain a Low BG Index; and

determining the assessed risk of hypoglycemia based on the Low BG Index.

- 11) An apparatus for predicting a near future BG profile and the onset of hypoglycemia comprising:
  - 5 a BG history profile recording mechanism;
  - an insulin infusion and/or injection history profile recording mechanism;
  - a HR history profile recording mechanism;
  - a HRV history profile recording mechanism;
  - a near future BG profile prediction module for predicting the near future
- 10 BG profile using a first predetermined bio-mathematical routine; and
  - a hypoglycemia prediction module for predicting the onset of hypoglycemia based on an assessed risk of hypoglycemia, wherein the assessed risk of hypoglycemia is determined using a second predetermined bio-mathematical routine.
- 15 12) The apparatus of claim 11 further comprising an BG monitoring module associated with the BG history profile recording mechanism.
- 13) The apparatus of claim 11 further comprising an HRV determination module associated with the HRV history profile recording module, wherein the HRV determination module comprises an EKG which evaluates the power spectra of RR time series as an estimate of HRV.
- 20 14) The apparatus of claim 11 further comprising an insulin infusion module associated with the insulin infusion and/or injection history profile recording module, and a insulin-regulation module which adjusts insulin infusion based on the predicted near future BG profile and the predicted onset of hypoglycemia.
- 25 15) The apparatus of claim 11 further comprising a hypoglycemia risk assessment module which determines the assessed risk of hypoglycemia using the second predetermined bio-mathematical routine.

16) The apparatus of claim 15 wherein the hypoglycemia risk assessment module comprises:

- an interface for receiving data regarding a BG history profile;
- a scale transformation module for transforming the BG history profile

5 scale to obtain a symmetrical distribution scale;

- a BG Risk Function module for determining a Low BG Index; and
- a hypoglycemia risk classification module for determining the assessed risk of hypoglycemia based on the Low BG Index.

17) An apparatus for predicting a near future BG profile and the onset of hypoglycemia comprising:

- an interface for receiving data regarding BG history, insulin infusion and/or injection history, HR history, and HRV history profiles;
- a BG prediction module for predicting a near future BG profile using a first predetermined bio-mathematical routine; and

15 a hypoglycemia prediction module for predicting the onset of hypoglycemia in the near future based on an assessed risk of hypoglycemia, wherein the assessed risk of hypoglycemia is determined using a second predetermined bio-mathematical routine.

18) The apparatus of claim 17 further including a hypoglycemia risk assessment module for determining the assessed risk of hypoglycemia using the second predetermined bio-mathematical routine.

19) A method for assessing the risk of hypoglycemia based on a Low BG Index comprising the steps of:

- receiving and recording a BG history profile;
- transforming the BG history profile scale to obtain a symmetrical distribution scale;
- introducing a BG Risk Function to obtain a Low BG Index; and
- assessing the risk of hypoglycemia based on the Low BG Index.

- 20) An apparatus for assessing the risk of hypoglycemia based on a Low BG Index comprising:
- an interface for receiving a BG history profile;
  - a BG history profile scale transformation module for transforming the
- 5 BG history profile scale into a symmetrical distribution scale;
- a BG Risk Function module for obtaining a Low BG Index; and
  - a hypoglycemia risk classification module for determining the assessed risk of hypoglycemia based on the Low BG Index.